PDBP
Parkinson's Disease Biomarkers Program

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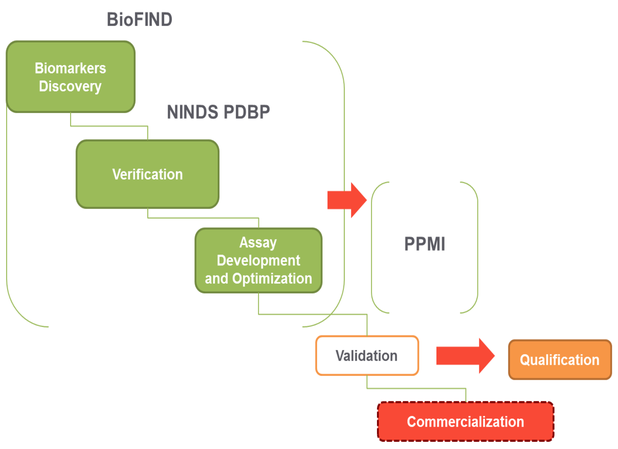
Introduction

The National Institute of Neurological Disorders and Stroke (NINDS), (USA) has established a Parkinson's Disease Biomarkers Program (PDBP) (see http://pdbp.ninds.nih.gov/). The overall purpose of the NINDS PDBP is to rapidly identify and develop potential biomarkers to improve the efficiency and outcome of Phase II clinical trials and advance therapeutic development for PD.

The NINDS PDBP will coordinate the efforts in the identification and development of diagnostic, progression or prognostic PD biomarkers and related assays by:

1) Standardizing data and biospecimen collection and management across new PD cohort studies
2) Enhancing efforts of current PD biomarker studies through ancillary projects that support additional well characterized biospecimen collection
3) Accelerating the discovery of new biomarkers
4) Fostering and expanding collaborative opportunities for all stakeholders.

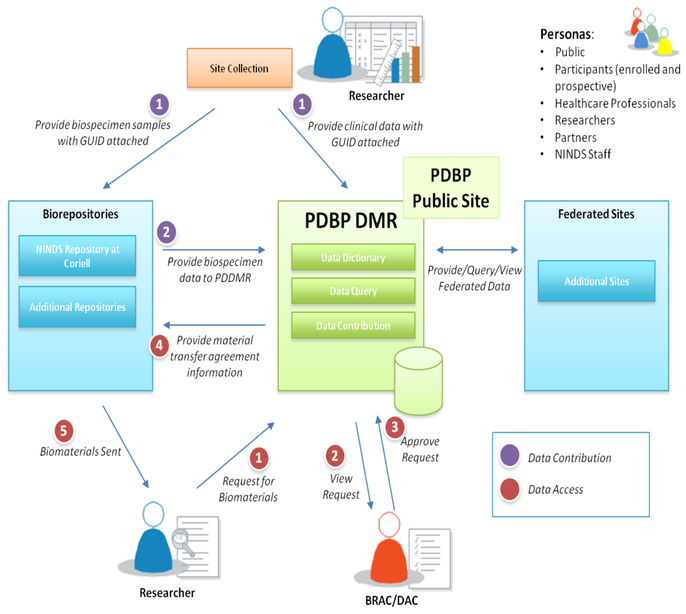
The Biomarkers Process



Structure

The NINDS PDBP includes four key components:

1) Biomarker hypothesis testing and collection of clinical data and biospecimens
2) Technology-based studies
3) Biospecimen banking and distribution through the NINDS Repository
4) Data management through a contract-supported Data Management Resource (DMR) for the standardization and sharing of biomarker-related data.



Data Management

With the DMR ProFoRMS tool one can efficiently:

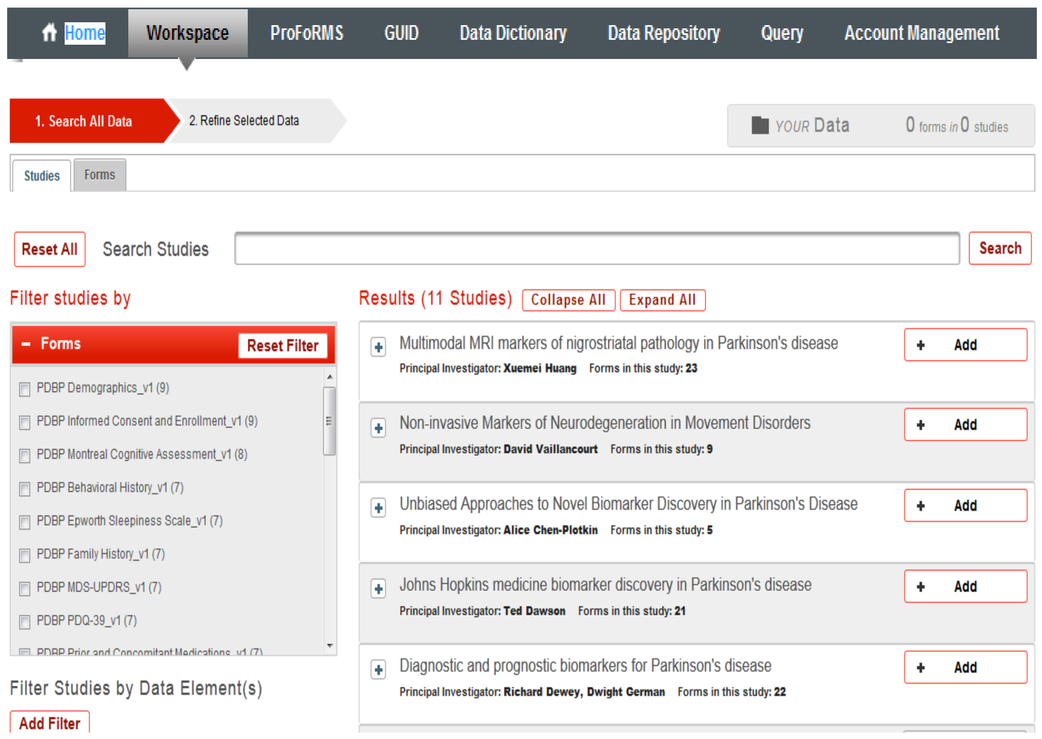
- Manage Studies, Subjects and Forms
- Collect Data
- View Reports

With the DMR Query tool one can efficiently

- Query and download data from individual PDBP studies
- Refine data searches based on clinical data element and associated values
- Search for biospecimens and order biospecimens via the Order Manager.

To Query Data in the PDBP DMR:

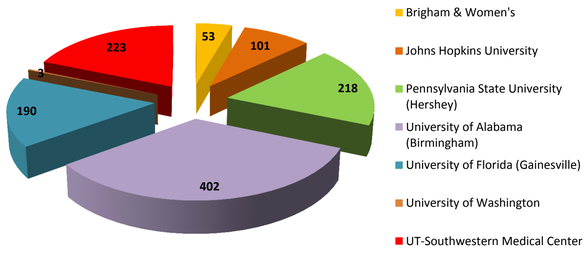
1. Simply select studies you wish to include in the query
2. Select the forms containing the data you wish to query
3. Refine your results by choosing specific data elements within the forms you selected
4. View your data in a 'datatable' or download in csv or excel format



Biospecimens

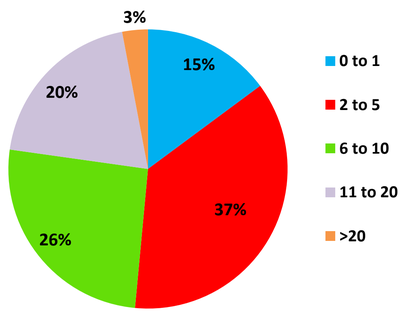
- Seven of the ten projects supported under the PDBP are clinical
- Over 1200 well characterized participants enrolled following standardized protocols
- Over 262 CSF samples and collectively more than 3800 RNA, DNA, plasma and serum samples available for use

Number of Participants enrolled in PDBP Projects as of January 2015

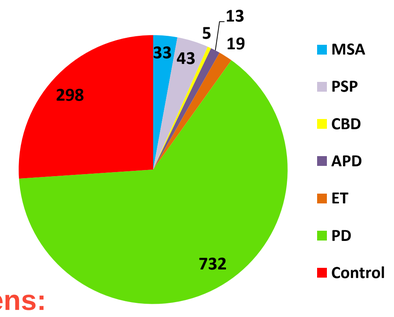


The chart graphically displays the number of participants per PDBP clinical site based on a total enrollment of 1207 participants as of January 22 2015. Enrollment as of January 22, 2015 represents 82% of the total anticipated enrollment for the program.

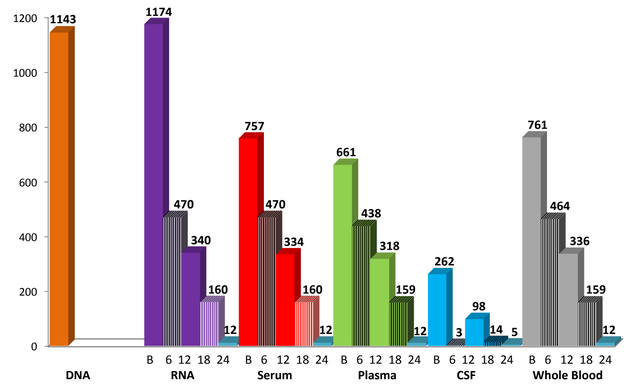
PDBP Participants – Years since PD diagnosis



Number of PDBP Participants based on diagnosis



Number of PDBP Biospecimens Available at the NINDS Biorepository as of January 2015



B = Baseline, 6 = 6 months, 12 = 12 months, 18 = 18 months, 24 = 24 months

To access clinical data and order biospecimens:

1. First request an account in the DMR
2. Log in and navigate to the query tool to access the NINDS Biorepository catalog
3. Select the samples you wish to order (samples are added to the order manager queue)
4. Fill in required fields to create the biosample order and submit request
5. Request will be reviewed by the Parkinson's Disease Biospecimen Resource Access Committee (PD BRAC)

Summary and Moving Forward

- The PDBP is a resource with a collection of detailed clinical data and extensive associated biospecimens on subjects with PD and controls. Researchers gain access to the PDBP DMR data by requesting an account. They can subsequently request biospecimens through a straightforward process. More information about requesting an account, ordering biospecimens and more generally, the NINDS PDBP, can be found on the PDBP website (https://pdbp.ninds.nih.gov).

- **PAR-14-259 Parkinson's Disease Biomarker Program (PDBP) Discovery Projects (U01):** This funding opportunity announcement (FOA) will support up to three years of study for the discovery, assay optimization, and replication stages required for the development of biological biomarkers for Parkinson's disease. Next due date – **May 4, 2015** http://grants.nih.gov/grants/guide/pa-files/PAR-14-259.html

- **Integration with existing biospecimen collections**
  PAR-14-340 Request to Access Parkinson's Disease Related-Biospecimens (X01)
  Using an X01 mechanism, investigators interested in PD biomarker discovery will have the ability to submit a single application for access to biosample resources from the NINDS PDBP, MJFF (BioFIND, DataTop, LRRK2 cohort), Banner Sun Health Brain/Tissue Bank and the Harvard Biomarker Neurodiscovery Initiative. **(Continuous Submission)**
  http://grants.nih.gov/grants/guide/pa-files/PAR-14-340.html

NIH National Institute of Neurological Disorders and Stroke